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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,197	08/07/2001	Neal Gutterson	MBI-008OUS	2170
47334	7590	11/22/2005	EXAMINER	
MENDEL 2 C/O MOFO SF 425 MARKET STREET SAN FRANCISCO, CA 94066			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/924,197	GUTTERSON ET AL.
Examiner	Art Unit	
David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

## Disposition of Claims

4)  Claim(s) 1-23 and 25-53 is/are pending in the application.  
4a) Of the above claim(s) 28-53 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-23 and 25-27 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 8/7/2001 is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR § 1.114***

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 23 August 2005 has been entered.
2. The claims as amended, filed on 21 July 2005, have been entered, are considered pending and are under examination.
3. Applicant's arguments (Remarks) filed on 21 July 2005 have been considered to the extent that they are directed to any rejection maintained in this Office action.
4. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments to the claims.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

6. Claims 28-53 remain withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8 April 2004.

7. This application contains claims 28-52 drawn to an invention nonelected with traverse in the response filed 8 April 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144) See MPEP § 821.01.

***Drawings***

8. New corrected drawings in compliance with 37 CFR § 1.121(d) are required in this application because the drawings as originally filed are considered informal. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. Although the drawings have previously been designated as acceptable, the instant Examiner does not find them so because of the hand written figure designations. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Claim Objections***

9. Claim 8 is objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case a nopaline synthase gene is not from an *Agrobacterium* species, it is from a Ti-plasmid, Ti-plasmids can be found in other bacterial species in the *Rhizobium* family.

***Claim Rejections - 35 USC § 112***

10. Claim 26 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is indefinite because it is unclear what the metes and bounds of "a nucleotide sequence of SEQ ID NO: 1" encompasses, in addition it is unclear what functional relationship "a nucleotide sequence of SEQ ID NO: 1" has in the expression cassette used in the method of claim 1 with the other structural features, hence the metes and bounds of the claim are unclear.

11. Claims 1-23 and 25-27 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of reducing expression of a target gene in a plant cell using an expression cassette comprising a targeting sequence operably linked 3' thereto to an inverted repeat having a sequence at least 30 base pairs in length, said inverted repeat prepared from a subsequence of a nopaline synthase 3' untranslated sequence, does not reasonably provide enablement for said method wherein the inverted repeat is operably linked 5' of the targeting sequence or wherein said inverted repeat is prepared from any subsequence of a nopaline synthase gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be

necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant provides limited guidance on how to practice the claimed method, in particular how to make and use the expression cassette used in said method. Applicant exemplifies in Figure 1 a construct wherein the inverted repeat is operably linked 3' of the targeting sequence, and said inverted repeat comprises a sequence from the 3' untranslated region of a nopaline synthase gene (page 19, 1<sup>st</sup> paragraph of the Remarks). Applicant states that the inverted repeat must have the ability to form a double stranded RNA in the cell (page 5, 2<sup>nd</sup> paragraph of the specification), but clearly one of skill in the art would recognize that 5' untranslated regions of the nopaline synthase gene, or any gene, would not have this required feature (see claims 6 and 18). Brummell *et al* (2003, The Plant Journal 33:793-800; having the inventive entity of the instant application in common) teach the heterologous 3'-untranslated region located 3' of the single-stranded targeting sequence induces highly efficient degradation of endogenous mRNAs homologous to the transgene (page 794, left column, 2<sup>nd</sup> paragraph). Brummell *et al* also teach that attaching the inverted repeat 5' of the targeting sequence to produce reduced expression of a target gene in a plant cell is not predictable and require further analysis (page 797, right column, 2<sup>nd</sup> paragraph). Applicant provides no evidence that the use of an inverted repeat 5' of the targeting

sequence will function in the claimed method. Applicant provides no evidence that using sequences of the nopaline synthase gene other than the 3' untranslated region will in the inverted repeat will function in the claimed method. Hence, given the unpredictability of the art, the limited teachings by Applicant, the general knowledge of one of ordinary skill in the art and the lack of working examples for the full breadth of the claimed method it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make expression cassettes to use the in the method as broadly claimed. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.".

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER



David H. Kruse, Ph.D.  
10 November 2005

13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.